

REMARKS

This responds to the Office Action dated March 3, 2003. Claims 8, 9, 12, 13, 27, 28 and 29 are amended. No claims are canceled. No claims are added. As a result, claims 1 – 35 remain pending in this application.

Objection to the Abstract

The Office Action objected to the Abstract as lacking sufficient detail. (*See* Office Action ¶1.) Accordingly, Applicant has provided the requested additional detail, which Applicant submits is fully supported by the specification of the present patent application as filed. Accordingly, Applicant respectfully requests withdrawal of this basis of objection to the Abstract.

§112 Rejection of the Claims

Claims 8, 9, 12-15, and 27-29 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

1. The rejection asserts that claim 8 lacks antecedent basis for “the activity signal” and “the subject’s activity.” (*See* Office Action ¶2.) Applicant has amended claim 8 to provide appropriate antecedent basis. Because such amendments merely provide antecedent basis for language already present, Applicant respectfully submits that such amendments are non-narrowing. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of claim 8.

2. The rejection asserts that claim 9 lacks antecedent basis for “the detecting” and “the activity signal.” (*See* Office Action ¶2.) Applicant has amended claim 9 to provide appropriate antecedent basis. Because such amendments merely provide antecedent basis for language already present, Applicant respectfully submits that such amendments are non-narrowing. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of claim 9.

3. The rejection asserts that claims 12, 13, 27, 28, and 29 are unclear as to antecedence. Applicant has amended these claims to clarify such antecedence, and submits that such claim amendments are non-narrowing. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of claims 12, 13, 27, 28, and 29.

§102 Rejection of the Claims

1. Claims 1-10, 13, 17-27 and 31-35 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Yerich et al. (U.S. Patent No. 5,562,711). Applicant traverses.

Regarding claims 1-10 and 13, Applicant can find no disclosure in Yerich et al. of detecting, in a subject, a condition correlative to hypotension, as recited or incorporated in these claims. Applicant also can find no disclosure in Yerich et al. of adjusting, in response to the detected condition correlative to hypotension, a rate response factor relating: (a) a pacing rate at which stimulations are delivered to the subject's heart; to (b) a sensor signal that is correlative to the subject's metabolic need for cardiac output as recited or incorporated in claims 1-10 and 13. Because the rejection using Yerich et al. does not disclose all elements of these claims, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Regarding claims 17-27, Applicant can find no disclosure in Yerich et al. of a hypotension condition detection circuit to detect a hypotension condition in a subject and to provide a hypotension detection indicator, as recited or incorporated in these claims. Applicant also can find no disclosure in Yerich et al. of a controller including a rate response factor to relate a component of the first sensor signal to the indicated rate, the rate response factor being adjusted by the controller in response to the hypotension condition indicator, as recited or incorporated in claims 17-27. Because the rejection using Yerich et al. does not disclose all elements of these claims, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Regarding claims 31-35, Applicant can find no disclosure in Yerich et al. of a means for detecting a hypotension in a subject and providing a responsive hypotension detection indicator, as recited or incorporated in these claims. Applicant also can find no disclosure in Yerich et al. of a controller including a rate response factor to relate a component of the first sensor signal to the indicated rate, the rate response factor being adjusted by the controller in response to the hypotension condition indicator, as recited or incorporated in claims 31-35. Because the rejection using Yerich et al. does not disclose all elements of these claims, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Regarding claims 3, 4, and 18 the rejection asserts that "it is inherent changes in tidal volume are impacted by fluid shifting to and from the lungs." (See Office Action ¶ 4.)

Applicant disagrees with this assertion. Applicant can find no such express or inherent disclosure in Yerich et al. To the extent that this assertion relies on the Examiner's personal knowledge, Applicant objects to any such reliance on Official Notice and respectfully requests a reference supporting such a teaching or suggestion. *See* M.P.E.P. § 2144.03. Moreover, even if support for such an assertion could be found in such a reference, Yerich et al. still fails to disclose responding to a detected hypotension by adjusting a rate-response factor, as discussed above. Because the rejection using Yerich et al. does not disclose all elements of claims 3, 4, and 18, Applicant respectfully requests withdrawal of this rejection of these claims.

Also, regarding claims 3, 4, and 18, the rejection asserts that "baseline values are defined for the physical and metabolic demand." (*See* Office Action ¶ 4.) However, the specification of the present patent application expressly distinguishes the "baseline portion" of the thoracic impedance from other higher frequency components of the thoracic impedance that are substantially influenced by the patient's breathing. (*See* Application at page 8, lines 17 – 27). The rejection itself recognizes that Yerich et al. discloses only measuring these higher frequency components of thoracic impedance:

The lowpass filtering of the impedance signal yields the respiratory rate while the highpass filtering of the same signal yields the patient's cardiac function . . . The low-pass filter *has a bandpass* of 0.05 to 0.8 Hz.

(Office Action ¶ 4.) Because the bandpass filtering of Yerich et al. intentionally attenuates the lower frequency baseline thoracic impedance referred to in claims 4 and 18, Yerich et al. actually teaches away from the subject matter recited in these claims. Moreover, not only can Applicant find no disclosure in Yerich et al. of using the baseline portion of the thoracic impedance, Applicant further cannot find any disclosure using an increase in the baseline portion of the thoracic impedance, as recited in claim 4. Accordingly, Applicant respectfully requests withdrawal of this rejection of these claims.

Regarding claims 5-7, 21 and 23, the rejection notes that Yerich et al.'s "low-pass filter has a bandpass of 0.05 to 0.8 Hz." (*See* Office Action ¶ 4.) Thus, the rejection itself admits that Yerich et al. discloses a bandpass filter, rather than the lowpass filter recited or incorporated in claims 21 and 23, and that Yerich et al. actually attenuates the baseline signal recited or incorporated claims 5-7. Because the rejection using Yerich et

al. has not disclosed all elements of these claims, Applicant respectfully requests withdrawal of this basis of rejection of these claims and, for similar reasons, of claim 20.

Regarding claims 9 and 26, the rejection notes that Yerich et al.'s "threshold values are counted to determine appropriateness of pacing rate." (*See* Office Action ¶ 4.) However, Applicant can find no disclosure in Yerich et al. of comparing substantially instantaneous and long-term components of an activity signal, or of deeming the detected condition to be correlative to hypotension when a first signal magnitude from the substantially instantaneous component of the activity signal exceeds a first threshold and a second threshold exceeds a second signal magnitude from the long-term component of the activity signal. Because the rejection using Yerich et al. has not disclosed all elements of these claims, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Regarding claims 13 and 27, the rejection states that in Yerich et al. "the acceleration parameter modifies the pacing rate." (*See* Office Action ¶ 4.) However, Applicant can find no disclosure in Yerich et al. of increasing a pacing rate response parameter in response to a detected hypotension, as recited or incorporated in these claims. Because the rejection using Yerich et al. has not disclosed all elements of these claims, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

2. Claims 1-8, 10-12, 17-23, 25, 27 and 31-35 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Combs et al. (U.S. Patent No. 5,957,861). Applicant traverses.

Regarding claims 1-4, Applicant can find no disclosure in Combs et al. of detecting hypotension or adjusting rate response factor in response to detected hypotension. Combs et al. apparently pertains to discerning edema. (*See* Combs et al. at Abstract). Moreover, Combs et al. states that pulmonary edema refers to fluid accumulation in the lungs. (*See, e.g.,* Combs et al. at column 1, lines 27-36.). By contrast, claim 1 of the present patent application refers to hypotension. The specification of the present patent application notes that hypotension refers to "low blood pressure" or "too-low intravascular fluid tension," which is often associated with a fluid shift away from the thorax. (*See* Application at page 2, lines 25-26; *see also* page 8, line 28, *see also* page 9, lines 1-16.) Therefore, Combs et al.'s discerning edema fails to disclose—

and actually teaches away from—detecting hypotension. Moreover, regarding the rejection’s assertion regarding claim 4 that “the baseline impedance is determined with adequate sampling” (Office Action ¶5), Applicant submits that, as discussed above with respect to Yerich et al., the specification of the present patent application expressly distinguishes the “baseline portion” of the thoracic impedance from other higher frequency components of the thoracic impedance that are substantially influenced by the patient’s breathing. (See Application at page 8, lines 17 – 27). By contrast, Combs et al. teaches discerning edema by evaluating respiratory rate and, therefore, actually teaches away from claim 4 of the present patent application. Because Combs et al. fails to disclose all elements of claims 1-4, Applicant respectfully requests withdrawal of this basis of rejection.

Regarding claims 5-7 and 21-23, the rejection states that “the low pass filter has a band-pass of 0.05 Hz to 0.5 Hz.” (Office Action ¶ 5.) Thus, the rejection itself admits that Combs et al. discloses a bandpass filter, rather than the lowpass filter recited or incorporated in claims 21-23, and that Combs et al. actually attenuates the baseline signal recited or incorporated claims 5-7. Because the rejection using Combs et al. has not disclosed all elements of these claims, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Regarding claims 11 and 12, the rejection asserts that “in Combs et al., “edema in the lungs is noted to impact blood pressure, hence creating hypotension when the pressure is low and hypertension when the pressure is high (c 8, ll 37-48.)” (Office Action ¶ 5.) Applicant traverses this assertion that Combs et al. discloses that edema impacts blood pressure. The cited portion of Combs et al. states:

if the edema level has changed greatly within a short period of time and the pressure values confirm that there is a physiologic problem, a drug pump can add diuretic as well as blood pressure medicaments to the patient’s body automatically, whereas if the blood pressure has not increased, only the diuretic can be added.

(Combs et al. at column 8, lines 41-46.) This passage fails to disclose that edema impacts blood pressure. Instead, it apparently merely notes that edema and blood pressure can be separately treated by a diuretic and blood pressure medicaments, respectively. Applicant can find no disclosure in Combs et al. of detecting the condition correlative to hypotension, including detecting a condition correlative both to a hypotension associated with a change in a subject’s

posture and to a hypotension that is not associated with a change in the subject's posture, as recited or incorporated in claims 11 and 12. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

In sum, Applicant respectfully submits that Combs et al. fails to disclose all elements of the rejected claims 1-8, 10-12, 17-23, 25, 27 and 31-35, the respiration detection of Combs et al. actually teaches away from using the baseline thoracic impedance associated with thoracic fluid shift, and the Combs et al. reference has been misapplied for the proposition that edema in the lungs affects blood pressure. Therefore, Applicant respectfully requests withdrawal of this basis of rejection.

3. Claims 1-4, 7, 8, 10-13, 17-19, 23-25, 27 and 31-35 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Pitts Crick et al. (U.S. Patent No. 6,104,949). Applicant traverses.

Applicant notes that the rejection recognizes that Pitts Crick et al. is directed toward diagnosing and treating congestive heart failure (CHF) by using impedance to detect pulmonary edema. (See Office Action ¶ 6.) However, pulmonary edema refers to fluid accumulation in the lungs. (See, e.g., Combs et al. at column 1, lines 27-36.) By contrast, claims 1-4, 7, 8, 10-13, 17-19, 23-25, 27 and 31-35 recite or incorporate adjusting a rate-response factor based at least in part on a detected hypotension, which is associated with a fluid shift away from the thorax. Therefore, Pitts Crick et al. does not disclose—and actually teaches away from—the subject matter of these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Regarding claim 4, the rejection asserts that Pitts Crick et al. discloses that “the baseline is determined based on averages.” (See Office Action ¶6.) Nonetheless, Applicant can find no disclosure in Pitts Crick et al. of detecting an increase in a baseline portion of a thoracic impedance, as is typically associated with a fluid shift away from the thorax. Instead, Pitts Crick et al. discloses detecting the fluid accumulation associated with edema by its associated decrease in thoracic impedance. (See Pitts Crick et al. at column 2, line 66 through column 3, line 6.) Therefore, Pitts Crick et al. does not disclose—and actually teaches away from—the subject matter of claim 4. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of claim 4.

4. Claims 1-4, 8, 10, 17-19 and 23-25 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Erlebacher (U.S. Patent No. 6,473,640). Applicant traverses.

The rejection recognizes that Erlebacher is directed toward a device for detecting and monitoring of CHF and fluid accumulation associated with pulmonary edema (*See Office Action ¶ 7.*) However, because claims 1-4, 8, 10, 17-19 and 23-25 pertain to hypotension, which is associated with fluid shifts away from the thorax, Applicant submits that Erlebacher fails to disclose all elements of these claims, for the same reasons discussed above with respect to Pitts Crick et al. Accordingly, Applicant respectfully requests withdrawal of this rejection.

As an additional note, Applicant notes that the present patent application has a filing date of June 12, 2001, and claims priority from U.S. Patent Application Serial Number 09/832,365, which has a filing date of April 10, 2001. Erlebacher did not issue until October 29, 2002. Consequently, Erlebacher is available as prior art (if at all) only under 35 U.S.C. 102(e). Therefore, Applicant does not admit that the cited Erlebacher reference is prior art, and Applicant reserves the right to "swear behind" Erlebacher as provided for under 37 C.F.R. 1.131.

§103 Rejection of the Claims

Claims 14-16 and 28-30 were rejected under 35 U.S.C. 103(a) as obvious over Yerich et al. in view of Kieval (U.S. Patent No. 5,800,464). Applicant traverses. As discussed above, Applicant can find no disclosure, teaching, or suggestion in Yerich et al. and/or Kieval of, among other things, detecting hypotension and responsively adjusting a rate-response factor, as recited or incorporated in these claims.

Moreover, the rejection alleges that "Kieval teaches hyperpolarization therapy using stepped and gradual pacing for the purpose of allowing the cardiac tissue to slowly adjusting to the therapeutic energy." (Office Action ¶ 9.) Kieval is apparently directed toward gradually increasing the energy of successive pacing pulses. (*See Kieval at Abstract.*) However, the present claims 14-16 and 28-30 recite or incorporate stepping a rate response factor, where the rate response factor relates: (a) a pacing rate at which stimulations are delivered to the subject's heart; to (b) a sensor signal that is correlative to the subject's metabolic need for cardiac output. Applicant can find no such disclosure, teaching, or suggestion in Kieval.

Because the cited references fail to disclose all elements of claims 14-16 and 28-30, Applicant submits that these claims are not *prima facie* obvious over Yerich et al. and/or Kieval. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612-373-6951) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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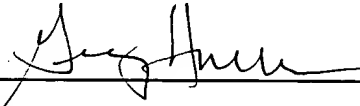
612-373-6951

Date June 3, 2003

By 
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 3rd day of June, 2003.

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